DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Crosstex International
Mr. Michael Nolan
Research and Development Coordinator
6789 West Henrietta Road
Rush, NY 14543

Re: K140620
Trade/Device Name: SporView® Plus BI Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological Sterilization Process Indicator
Regulatory Class: II
Product Code: FRC
Dated: July 9, 2014
Received: July 11, 2014

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K140620

Device Trade Name: SporView® *Plus* Steam BI Test Pack

INDICATIONS FOR USE:

The SPSmedical SporView® *Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine monitoring and sterilizer qualification testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time.

Prescription Use _____ and/or Over the Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Sreekanth Gutala -S

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DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.08.06 11:54:54 -04'00'

510(k) Summary

SUBMITTER INFORMATION:

SPSmedical Supply Corp.
a division of Crosstex International
6789 West Henrietta Road
Rush, NY 14543 U.S.A.

Contact: Michael G. Nolan
Research and Development Coordinator
Phone: (800) 722-1529
Fax: (585) 359-0167

Date of Summary: August 5, 2014

DEVICE INFORMATION:

Device Trade Name:	SporView® *Plus* Steam BI Test Pack
Common Name:	Biological Test Pack
Classification Name:	Biological Sterilization Process Indicator 21 CFR § 880.2800(a)
Review Panel:	General Hospital
Product Code:	FRC
Device Class:	II

PREDICATE DEVICE:

The SPSmedical SporView® *Plus* BI Test Pack cleared under K051173.

DEVICE DESCRIPTION:

Description of change to the legally marketed predicate device—The SporView® *Plus* BI Test Pack cleared under K051173 contained a biological which required 24 hours of incubation time. This submission aims to replace that biological with the SporView® 10 Steam Self Contained Biological Indicator within the SporView® *Plus* BI Test Pack.

Functionality—The SporView® *Plus* BI Test Pack is a single use device designed to assess the effective performance of both gravity displacement and pre-vacuum steam sterilization processes.

Scientific Concepts—The SporView® *Plus* BI Test Pack provides a defined challenge to the sterilization process that is equal to or greater than the challenge posed by the AAMI reference PCD.

Physical Characteristics—The SporView® *Plus* BI Test Pack consists of layers of paper with a biological indicator and a load record card with chemical integrator placed in the center and all placed within an exterior containment box. A process indicator label placed on the containment box alerts users if a pack has been exposed to the sterilization process. The approximate dimensions of the pack are 4-5/8" x 7/8" x 6-1/4". The load record card is used to record all the detailed information from the sterilization cycle.

Performance Characteristics—The performance of the SporView® *Plus* BI Test Pack has been demonstrated to be equivalent to that of the AAMI reference PCD.

INTENDED USE:

NOTE: The intended use of the modified device, as described in the labeling, has not changed as a result of the modification.

The SPSmedical SporView® *Plus* Steam BI Test Pack is designed to monitor sterilization cycles in both gravity displacement and pre-vacuum steam sterilizers. It is to be used for routine monitoring and qualification testing of steam sterilizers.

TECHNICAL CHARACTERISTICS:

The outer box and layers of paper within the SporView® *Plus* BI Test Pack provide a significant challenge to air removal and subsequent steam penetration of prevacuum and gravity steam sterilizers. The Load Record Card with STEAM*Plus*™ Steam Integrator allow for an immediate observation of cycle performance with 10 hour incubation results of the SporView® 10 Steam Self Contained Biological Indicator offers complete assurance of cycle performance. The external process indicator alerts users when a pack has seen the sterilization process.

510(k) Summary

RECOMMENDED STORAGE CONDITIONS:

Store in a cool, dry place (15-30°C).

NON-CLINICAL TESTING:

Validation of the SporView® *Plus* BI Test Pack was accomplished with performance testing in steam gravity and prevacuum cycles operating at 250°F/121°C and 270°F/132°C. All results from testing meet the predetermined acceptance criteria. All testing followed the FDA Guidance document for Industry and FDA Staff entitled, "Biological Indicator (BI) Premarket Notification [510(k)] Submissions," issued on October 4, 2007. Testing consisted of running test packs and control packs (predicate) within the same cycles for pass, fail and partial cycles at the end of the product's shelf life of eighteen (18) months.

COMPONENTS:

The SporView® *Plus* BI Test Pack Components are equivalent to its original filing with the exception of the SporView® Steam Self Contained Biological Indicator.

- Subject of this change SporView® 10 Steam Self Contained Biological Indicator (K122024)
- Load Record Card with STEAM*Plus*™ Steam Integrator (K051173)
- External Process Indicator with lot and expiration information (K051173)
- Outer box and paper inserts (K051173)

SUBSTANTIAL EQUIVALENCE DISCUSSION

SPSmedical has identified the SporView® *Plus* BI Test Pack (K051173) as the (primary) predicate device. We believe the predicate device to be substantially equivalent to the subject device in terms of their intended use and functional characteristics as they are essentially the same device. See a comparison of the subject device to the predicate device (K051173) in Table 1.

PREDICATE I.D.:

Trade Name:	SporView® *Plus* BI Test Pack
Model No.:	SBT-025 (25 controls) & SBT-255 (5 controls)
Submitter/holder:	SPSmedical Supply Corp. 6789 West Henrietta Road Rush, NY 14543 U.S.A. Phone: (585) 359-0130 Fax: (585) 359-0167
510(k) No.:	K051173

COMPARISON OF INDICATIONS FOR USE (IFU):

Predicate IFU *K051173*—The SPSmedical SporView® *Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine and challenge testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time or longer and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time or longer.

Subject IFU *K140620*—The SPSmedical SporView® *Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine monitoring and sterilizer qualification testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time.

Compared to the predicate the subject device has changes for clarity but is otherwise the same.

DESIGN DIFFERENCES PREDICATE VS. SUBJECT DEVICE:

The Predicate Device contains the SporView® Steam Self-Contained Biological Indicator which was cleared under K070595. The Subject Device contains the SporView® 10 Steam Self Contained Biological Indicator which was cleared under K122024.

510(k) Summary

FUNCTIONAL CHARACTERISTICS:

The SporView® *Plus* Steam BI Test Pack is designed to create a significant challenge to air removal and steam penetration. Like the AAMI test pack, the SPSmedical SporView® *Plus* Steam BI Test Pack provides a significant challenge to the steam sterilization process and is used for routine monitoring and qualification testing of gravity displacement and pre-vacuum steam sterilizers. Both have internal steam monitoring components located within the center of the pack and chemical indicator located on the pack.

DISCUSSION:

SPSmedical is claiming substantial equivalence for its SporView® *Plus* Steam BI Test Pack to the original SporView® *Plus* Steam BI Test Pack (K051173) based on test data obtained during validation studies. We have demonstrated with testing that the SporView® *Plus* Steam BI Test Pack performs consistently when run in steam gravity and prevacuum cycles operating at 250°F/121°C and 270°F/132°C for pass, fail and partial cycles.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

The SporView® *Plus* Steam BI Test Pack has the same intended use and characteristics as the predicate SporView® *Plus* Steam BI Test Pack. They both provide a significant challenge to the steam sterilization process. Testing data demonstrates the subject device is substantially equivalent to the predicate device.

TABLE 1—COMPARISON OF THE SUBJECT DEVICE TO THE PREDICATE

Element	Subject Device (K140620)	Predicate (K051173)
Intended use: method of sterilization process parameters	Steam 250°F/121°C 30 minutes 270°F/132°C 4 minutes	Steam 250°F/121°C 30 minutes 270°F/132°C 4 minutes
Indications for Use (IFU)	The SPSmedical SporView® *Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine monitoring and sterilizer qualification testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time.	The SPSmedical SporView® *Plus* Steam BI Test Pack with STEAM*Plus* Integrator is indicated for use in routine and challenge testing of steam gravity displacement cycles at 121°C/250°F for 30 minutes exposure time or longer and for use in pre-vacuum steam sterilization cycles at 132°C/270°F for 4 minutes exposure time or longer.
Labeling	Equivalent, except for 10 hour incubation time	Equivalent, except for 24 hour incubation time
Organism: spore species & strain	*Geobacillus Stearothermophilus* ATCC 7953	*Geobacillus Stearothermophilus* ATCC 7953
Viable spore population	10^5 or greater	10^5 or greater
Resistance characteristics	Equivalent, calculated per USP	Equivalent, calculated per USP
Culture Conditions	55-60°C	55-60°C
Carrier Materials	Whatman Paper	Whatman Paper
Packaging: primary & secondary	Equivalent	Equivalent
Storage	Equivalent	Equivalent
Shelf Life	Eighteen (18) months	Eighteen (18) months